DEC 1 3 2001

K013992

510(k) Submission for

Nichols Advantage® Chemiluminescence Bio-Intact PTH (1-84) Immunoassay

Nichols Institute Diagnostics, Inc.

November 5, 2001

SUMMARY STATEMENT OF SAFETY AND EFFECTIVENESS

The sponsor, Nichols Institute Diagnostics, Inc., has developed, manufactured and tested under current Good Manufacturing Practices/Quality System Regulations (cGMP/QSR) an in vitro diagnostic (IVD) device to quantitatively assay for parathyroid hormone (PTH) in serum and EDTA plasma.

The trade name is: Nichols Advantage® Chemiluminescence Bio-Intact Parathyroid Hormone (1-84) Immunoassay, having a common name of: Bio-Intact PTH (1-84) Immunoassay. This is a Class II in vitro diagnostic (IVD) medical device, as per 21 CFR 862.1545 with a Product Code of 75 CEW. This Bio-Intact PTH (1-84) Immunoassay is intended for use with the Nichols Advantage® Specialty System for measurement of parathyroid hormone levels in patient serum (preferred) or plasma, for differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism.

The Nichols Advantage® Chemiluminescence Bio-Intact PTH (1-84) Immunoassay is a two-site immuno-chemiluminometric IVD device with sufficient reagents for 100 tests, that are performed entirely on the Nichols Advantage® Specialty System (K961142; cleared February 18, 1997). Two goat polyclonal antibodies directed at epitopes on intact human PTH are used. One antibody ("capture reagent") is chemically labeled with biotin, while the second antibody ("detection reagent") is chemically labeled with acridinium ester for subsequent quantitative measurements. A sample of patient serum (preferred) or plasma is added to an assay cuvette, followed by addition of the two goat anti-PTH antibodies and the streptavidin-coated magnetic particles. The reaction mixture is allowed to incubate for 30 minutes at 37°C. Because of the high affinity interaction between biotin-labeled antibody and streptavidin, the sandwich complex is captured onto the streptavidin-coated magnetic particles. The captured complex bound to the magnetic particle passes to the Nichols Specialty System for a wash to remove unbound components and/or patient substances. The washed captured complex bound to the magnetic particles within the cuvette wells are analyzed Nichols Specialty System's luminometer via the automatic injection of reagents that initiate the acridinium-based chemiluminescence quantitative reaction. The light is measured by the Nichols Specialty System's luminometer and expressed as Relative Light Units (RLU). The amount of PTH bound-labeled antibody is directly proportional to the concentration of intact PTH in the serum or plasma sample.

In-house testing of the Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay demonstrated Within-Run precision not greater than 4% at a dose higher than 5 pg PTH/mL, and a Total Precision of not greater than 8.5% at a dose higher than 5 pg PTH/mL, with a throughput of about 180 results per hour. The Limit of Detection for this Bio-Intact (1-84) PTH Immunoassay was estimated to be at or below 1.5 pg/mL, with Recovery ranging from 93% to 103%, and Parallelism at 92% to 111%. No High Dose Hook Effect was observed up to 100,000 pg PTH/mL. The PTH fragment 7-84 did not interfere in this assay at a dose up to 3000 pg/mL; PTH fragments 39-68, 53-84, 44-68, 39-84 gave minimal interference. Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay (y) was compared to predicate Nichols Intact PTH Immunoassay (x), previously FDA cleared and currently marketed for Intact PTH assay. Three hundred five (305) patient serum samples were assayed by both methods using insert directions without modifications. The range of values observed with the predicate Intact PTH Immunoassay was 5.0 to 1387 pg/mL, while the range with the Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay was 3.0 to 746 pg/mL. Passing Bablok regression analysis of these data yielded an equation of $y = 0.66x - 0.6$ (95% confidence intervals of the slope and intercept were 0.64 to 0.68, and -1.1 to -0.2 respectively). Pearson's correlation coefficient (r) of the paired data was 0.97 (95% confidence interval was 0.96 to 0.98), demonstrating that this Bio-Intact PTH (1-84) Immunoassay provided essentially equivalent results to an approved predicate Intact PTH (1-84) Immunoassay.

Additional information on this Nichols Advantage® Bio-Intact PTH (1-84) Immunoassay submission may be obtained by contacting Mr. Robert Schmidt, Vice President of Quality Systems, Nichols Institute Diagnostics, Inc. by telephone at 1-949-240-5417 or by telefax at 1-949-240-5271.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Nichols Institute Diagnostics
c/o Raymond Wilson, Pharm.D.
California Department of Health
Medical Device Safety Section
Food and Drug Branch
P.O. Box 942732 (MS-357)
Sacramento, CA 94234

DEC 1 3 2001

Re: k013992
Trade/Device Name: Nichols Advantage® Chemiluminescence Bio-Intact PTH (1-84) Immunoassay
Regulation Number: 21 CFR 862.1545
Regulation Name: Parathyroid hormone test system
Regulatory Class: Class II
Product Code: CEW
Dated: November 29, 2001
Received: December 4, 2001

Dear Dr. Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

4.0 INDICATIONS FOR USE STATEMENT

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K013992

Device Name: Nichols Advantage® Chemiluminescence Bio-Intact PTH (1-84) Immunoassay

Indications For Use:

The Nichols Advantage® Bio-Intact PTH (1-84) immunometric assay is intended for use with the Nichols Advantage® Specialty System to measure the levels of parathyroid hormone in serum and EDTA plasma. Measurements of parathyroid hormone levels are used in the differential diagnosis of hypercalcemia (abnormally high levels of calcium in the blood) and hypocalcemia (abnormally low levels of calcium in the blood) resulting from disorders of calcium metabolism. Assay results should be used in conjunction with other clinical data to assist the clinician in making individual patient management decisions.

Thomas C. Gross for Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013992

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)